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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 09/820,210 | 03/27/2001 | Peter Wagner | 20144-000910 | 3853 |
| 20350 | 7590 | 01/26/2005 | EXAMINER | |
| TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834 | | | CEPERLEY, MARY | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1641 | | |

DATE MAILED: 01/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|-----------------|---------------|
| | 09/820,210 | WAGNER ET AL. |
| Examiner | Art Unit | |
| Mary (Molly) E. Ceperley | 1641 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 October 2004.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,5,9,26,27 and 78 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,5,9,26,27 and 78 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ .

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ .
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____ .

1) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 12, 2004 has been entered.

2) Although specific claims are cited and discussed in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1, 5, 9, 26, 27 and 78 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The structure which appears in claim 1 as amended on October 01, 2004 corresponds to the structure of formula (I) of original claim 1 namely, $(X-L^1)-W-(L^2-Y)(L^3-Z)$. Thus, the term "NH-CH-CO" (the residue of glycine) of the structure of claim 1 as amended on October 01, 2004 corresponds to "W" defined as "a covalent core component" in original claim 1. However, the variable "W", as described and

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defined in the instant specification, does not include the glycine residue (NH-CH-CO) of amended claim 1. See the specification at page 23, lines 12-31. Although applicants state at page 11 of the October 01, 2004 Remarks that they "have amended claim 1 and 26 to include a core component that is the residue of an amino acid having a reactive functional group in the side chain", glycine ($\text{NH}_3^+ \text{-CH}_2\text{COO}^-$), the "core covalent component", is an amino acid that does not contain a side chain.

It is presumed from applicants' discussion at page 7 and page 5 (B. Support for the Amendments) of the October 01, 2004 Remarks and original claim 11 that the term "-L³-Z" of amended claim 1 is meant to be limited to the definitions: -(CH₂)₄-NH₂, -CH₂OH, -CH₂SH, -(CH₂)₁₋₂COOH and -CH₂(CH₃)-OH wherein the functional groups -NH₂, -OH, -SH and -COOH may be protected. Applicants are requested to verify this interpretation on the record.

6) Claims 26 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 26 is indefinite and confusing for the following reasons. In order for the "protein conjugate" of claim 26 to be operable for the purpose of the invention, the term "X" is a non-covalent protein tag binder...to a protein tag portion of a protein" should be changed to indicate that "X" specifically binds to a protein tag portion of the "Protein" moiety shown in the formula. Similarly, the claim language should reflect that the "protein tag" described in the definition of "Y" is present on the "Protein" moiety shown in the formula.

b) The exact structure of the "protein-conjugate" of claim 27 cannot be determined since there is no indication of where or how the protein is attached to the "heterofunctional crosslinking reagent". The claim language does not limit the point of attachment of the "protein" to any particular moiety of the "heterofunctional crosslinking reagent". If the claim were to be limited to the attachment of the "protein" to the "reagent" through the moiety "Y", the claim would be a duplicate of claim 26.

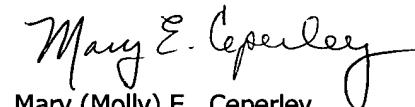
c) In claim 27, there is no antecedent basis in claim 1 for the term "group" and it is unclear exactly what is meant by this term.

7) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 21, 2005


Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641